RECEIVED
CENTRAL FAX CENTER
JUL 27 2004

OFFICIAL

8/6/04

PTO/SB/30 (09-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Request for Continued Examination (RCE) Transmittal

Address to:
Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Application Number	09/390,846
Filing Date	September 14, 1999
First Named Inventor	KOK, et al
Art Unit	1645
Examiner Name	N. MINNIFIELD
Attorney Docket Number	I-1995.150 US D1

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. Submission required under 37 CFR 1.114 Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).
   a. ☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.
      i. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
      ii. ☐ Other _____
   b. ☑ Enclosed
      i. ☐ Amendment/Reply
      ii. ☐ Affidavit(s)/ Declaration(s)
      iii. ☐ Information Disclosure Statement (IDS)
      iv. ☑ Other Amendment filed by US Mail 07/27/2004

2. Miscellaneous
   a. ☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)
   b. ☐ Other _____

3. Fees The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.
   The Director is hereby authorized to charge the following fees, or credit any overpayments, to
   a. ☑ Deposit Account No. 02-2334
      i. ☑ RCE fee required under 37 CFR 1.17(e)
      ii. ☐ Extension of time fee (37 CFR 1.136 and 1.17)
      iii. ☐ Other _____
   b. ☐ Check in the amount of $ _____ enclosed
   c. ☐ Payment by credit card (Form PTO-2038 enclosed)

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Name (Print/Type)	Mark W. Milstead	Registration No. (Attorney/Agent)	45,825
Signature		Date	July 27, 2004

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 or facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.

Name (Print/Type)	Diana Payne	Date	July 27, 2004
Signature			

09390846

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

KOK et al

Serial Number: 09/390,846 Group: 1645

Filed: September 14, 1999 Examiner: Minnifield, N.

For: COCCIDIOSIS POULTRY VACCINE

PETITION FOR REFUND TO DEPOSIT ACCOUNT UNDER 37 C.F.R. §1.26

Commissioner of Patents
Alexandria, VA 22313

October 20, 2004

Sir:

The undersigned hereby petitions for a refund to Deposit Account 02-2334 in the amount of $420.00 in connection with the above-identified application. Applicants respectfully submit the following remarks.

REMARKS

Applicants filed a Request for Continued Examination (RCE) by transmission of facsimile on July 27, 2004. On the RCE form Applicants checked the box "Other" with a typed note stating to enter "Amendment filed by US Mail 07/27/2004". USPTO charged Deposit Account $420.00 on August 25, 2004 for a two month

extension, in connection with the filing of the Request for Continued Examination faxed. 2004 OCT 29 AM 10:33

Applicants' response to the outstanding Office Action mailed February 27, 2004, was respectfully submitted having been extended two months, along with the cited references by first class U.S. mail on July 27, 2004. Upon receipt the USPTO again charged Deposit Account 02-2334 an additional $420.00 for a two month extension.

The result of the USPTO action was to charge deposit account 02-2334 a total of $840 for a two month extension.

Applicants have attached the supporting documentation to show overcharge.

Conclusion

Applicants respectfully request a $420 credit to deposit account 02-2334 because the USPTO double charged Applicants for a single two month extension.

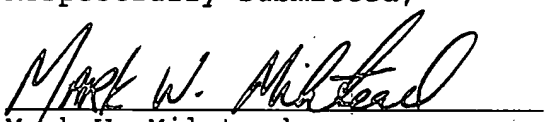
Should the Examiner believe that a conference would be helpful in advancing the prosecution of this application, he is invited to telephone Applicants' Attorney at the number below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2334 for any

additional

Applicants respectfully request the Examiner to consider the above petition and hereby authorize the Commissioner to credit Deposit Account 02-2334 in the amount of four hundred and twenty dollars.

Respectfully submitted,



Mark W. Milstead
Patent Counsel
Registration No.: 45,825

Akzo Nobel Pharma Patent Department
29160 Intervet Lane
PO Box 318
Millsboro, DE 19966
Tel: 302-934-4395
Fax: 302-934-4305

Enclosure: Request for Continued Examination Filed July 27, 2004 (1 page)
Fax Cover Sheet dated July 27, 2004 (1 page)
Fax History Report dated July 27, 2004 (1 page)
Certificate of Mailing dated July 27, 2004 (1 page)
Amendment dated July 27, 2004 (17 pages)
Copy of postcard acknowledging receipt of items mailed July 27, 2004 (1)

DIVISION

PTO/SB/30 (09-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Request for Continued Examination (RCE) Transmittal

Address to:
Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Application Number	09/390,846
Filing Date	September 14, 1999
First Named Inventor	KOK, et al
Art Unit	1645
Examiner Name	N. MINNIFIELD
Attorney Docket Number	I-1995.150 US D1

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. Submission required under 37 CFR 1.114 Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

   a. ☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

      i. ☐ Consider the arguments in the Appeal Brief or Rely Brief previously filed on _____

      ii. ☐ Other _____

   b. ☑ Enclosed

      i. ☐ Amendment/Reply

      ii. ☐ Affidavit(s)/ Declaration(s)

      iii. ☐ Information Disclosure Statement (IDS)

      iv. ☑ Other Amendment filed by US Mail 07/27/2004

2. Miscellaneous

   a. ☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

   b. ☐ Other _____

3. Fees The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

   a. ☑ The Director is hereby authorized to charge the following fees, or credit any overpayments, to Deposit Account No. 02-2334

      i. ☑ RCE fee required under 37 CFR 1.17(e)

      ii. ☐ Extension of time fee (37 CFR 1.136 and 1.17)

      iii. ☐ Other _____

   b. ☐ Check in the amount of $ _____ enclosed

   c. ☐ Payment by credit card (Form PTO-2038 enclosed)

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Name (Print/Type)	Mark W. Milstead	*Registration No. (Attorney/Agent)*	45,825
Signature	Mark W. Milstead	*Date*	July 27, 2004

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 or facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.

Name (Print/Type)	Diane Payne		
Signature	Diane Payne	Date	July 27, 2004

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Telefax Transmittal
Cover sheet

AKZO NOBEL

29160 Intervet Lane
P.O. Box 318
Millsboro, DE 19966-0318
(302) 934-8051

July 27, 2004

2...pages including cover sheet.

PERSON TO:	COMPANY/DEPT TO:	FAX NUMBER:
MAIL STOP RCE	Commissioner for Patents Art Unit: 1645	703-872-9306

PERSON FROM:	COMPANY/DEPT FROM:	FAX NUMBER:
Diane Payne	Patent Department	302-934-4305

USSN: 09/390,846

Attorney Docket No.: I-1995.150 US D1

Please accept the documents which follow in the above-identified application:

Request for Continued Examination (PTO SB30) (1 page)

Intervet

HP OfficeJet T Series
Personal Printer/Fax/Copier/Scanner

DIVISION

Fax History Report for
Intervet Inc.
934 4305
Jul 27 2004 2:31pm

Last Fax

Date	Time	Type	Identification	Duration	Pages	Result
Jul 27	2:30pm	Sent	917038729306	1:02	2	OK

Result:
OK - black and white fax
OK color - color fax

DIVISION

July 27, 2004

RE: KOK, et al
Attorney Docket No.: I-1995.150 US D1
USSN: 09/390,846

Receipt is acknowledged of the following papers in the above-identified application:

Amendment (17 pages)
Cited Reference Schaap et al Journal Article (14 pages)
Certificate of Mailing (1 page)

Certificate of Mailing under 37 CFR 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

on July 27, 2004.
Date

Diane Payne
Signature

Diane Payne
Typed or printed name of person signing Certificate

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Attorney Docket No.: I-1995.150 US D1
USSN: 09/390,846

Amendment (17 pages)
Cited Reference Schaap et al Journal Article (14 pages)
Self-Addressed Stamped Postcard

Attorney Docket NO. I/95150-US/D1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:
KOK et al.

Serial No.:	09/390,846	Group:	1645
Filed:	September 14, 1999	Examiner:	N. Minnifield
For:	COCCIDIOSIS POULTRY VACCINE		

AMENDMENT UNDER 37 C.F.R. §1.116

Honorable Commissioner of Patents
Alexandria, VA 22313

July 27, 2004

Sir:

In response to the outstanding Office Action mailed February 27, 2004, the period for response having been extended two months to July 27, 2004, Applicants respectfully submit the following amendment and remarks in connection with the above-identified application.

In the Claims

1. (Previously Presented) A protein expressed *in vitro*, comprising:

one or more immunoreactive and/or antigenic determinants of *Eimeria* lactate dehydrogenase (LDH), wherein said isolated protein is found intracellularly in Eimeria.

2. (Previously Presented) The protein according to claim 1, wherein the *Eimeria* species is *Eimeria acervulina*.

3. (Previously Presented) The protein according to claim 1, which comprises the amino acid sequence shown in SEQ ID NO:2, a biologically active variant, or an immunogenically active part sequence or variant.

4-10. (Canceled)

11. (Previously Presented) A vaccine for the protection of poultry against Coccidiosis comprising:

an effective amount of an isolated protein comprising one or more immunoreactive and/or antigenic determinants of Eimeria lactate dehydrogenase, wherein said isolated protein is found intracellularly in Eimeria.

12. (Canceled)

13. (Previously Presented) A process for the preparation of a coccidiosis vaccine, comprising:

formulating a protein according to claim 1 into a pharmaceutical preparation with immunizing activity.

14. (Canceled)

15. (Withdrawn) A method for the protection of poultry against coccidiosis, comprising:

administering to the poultry a vaccine according to claim 11.

16. (Previously Presented) The protein according to claim 1, wherein said protein has a molecular weight of about 37 kD.

17. (Previously Presented) An immunogenic fragment of Eimeria lactate dehydrogenase (LDH), wherein said LDH is immunogenically reactive with antiserum raised against the polypeptide of SEQ ID NO:2.

18. (Previously Presented) An immunogenic fragment of the protein according to claim 1, or a biologically active variant of said fragment.

19. (Previously Presented) The vaccine of claim 11, wherein the protein is present in pure form.

20. (Previously Presented) The vaccine of claim 11, further comprising a pharmaceutically acceptable carrier.

21. (Withdrawn) A method for the protection of coccidiosis, comprising:

administering to the poultry a vaccine according to claim 20.

22. (Canceled).

23. (Previously Presented) A vaccine for the protection of poultry against coccidiosis, comprising:

an effective amount of the protein according to claim 3.

24. (Previously Presented) The vaccine of claim 23, further comprising a pharmaceutically acceptable carrier.

25. (Withdrawn) A method for the protection of poultry against coccidiosis, comprising:

administering to the poultry a vaccine according to claim 24.

26. (New) A vaccine for the protection of poultry against coccidiosis, comprising:

an effective amount of the immunogenic fragment according to claim 17.

REMARKS

Upon entering the above amendment claims 1-3, 11, 13, 15-21 and 23-25 are pending in the present application. Applicants have canceled claims 14 and 22 with the above amendment and added new claim 26. Claims 1, 11 and 17 are independent claims.

Applicants have not raised any issue of new matter.

Applicants concurrently have filed a Request for Continued Examination (RCE) and wish the above amendment entered into the record and considered.

Foreign Priority

The Examiner reports that foreign priority documents have not been received. This application is a Division of U.S. Application 08/676,882, July 3, 1996, now U.S. Patent 6,100,241; therefore, Applicants respectfully request the Examiner to review the parent application to see if the certified foreign priority document is present. Applicants need to know, if 08/676,882 has an original foreign priority document in it file wrapper before Applicants can act.

Issue Under 35 U.S.C. §112, First Paragraph

Claims 3, 18, 23 and 24 stand rejected under 35 U.S.C. §112, first paragraph, because the specification allegedly fails to

provide an enabling disclosure for any fragment of the isolated protein. The Examiner has maintained the same rejection. Applicants traverse this assertion.

As stated in previous responses, the specification clearly enables an isolated 37kd protein from Eimeria acervulina consisting of the amino acid sequence set forth in SEQ ID NO.:2 and a vaccine containing the 37kd protein.

The Examiner asserts that the present disclosure fails to provide enablement of fragments and the one fragment present, GWIKQEEVDDIVQK, is not enabled for its use as a vaccine. Again Applicants direct the Examiner to page 8, line 31 through page 9, line 2 and page 14, last paragraph where this issue is addressed.

Applicants have previously presented decision from the Federal Circuit that supports Applicants' assertion for enablement. Applicants have considered the list of requirements for enablement set forth by the Examiner. Applicants assert that the parameters set forth are not the law. The requirement of indication each of fragment that will retain activity of the intact protein is wrong. It is unreasonable that each fragment must be identified and tested.

More importantly, Applicants are not inviting one to experiment. Applicants have set forth one fragment as admitted by the Examiner. Applicants have set forth disclosure that a skilled artisan would need to understand how to locate, isolate or synthesize and use immunogenic determinant by indicating this

is done by Kyte-Doolittle plots, by Hopp-Woods plots and by surface-exposure plots of the Eimeria LDH. Proof of the effectivity of using such tools was provided pointing to the paper by Margalit et al (1987, J. of Immunol., vol. 138, p.2213-2229.

Applicants respectfully submit the publication by Schaap et al. (2004, Parasitology, vol. 128, p. 603-616). This journal article was published after the priority date of the application. Schaap et al. describes the cloning and the sequences of LDH's from the Eimeria species acervulina, tenella and maxima. The identity between the amino acid (aa) sequences is described as "rather low" and as "extensively diverged" being between 66 and 80% aa identity. A multiple alignment of the aa sequences is presented in figure 2 (p. 606). The aa sequence of E. tenella LDH was used to model its 3D structure, which was compared to that of Plasmodium falciparum (Malaria) LDH. Remarkably, the E. tenella and P. falciparum LDH proteins share only 47% aa identity but have an almost identical 3 dimensional structure (see figure 3, page 609). The article asserts on page 609 (bottom of left column - through top of right column): although the primary structure (the aa sequence) is "substantially different", their 3D structures are "very similar". Schaap et al. recite in the middle of that same page: "In summary . . . only shows 47% identity . . . conserved active site features . . . predicted to be a molecule with very similar properties."

Therefore, Applicants respectfully submit the following as facts:

-the patent application shows effective vaccination with E. acervulina LDH

-the publication by Schaap et al. show aa sequences of LDH protein of two more Eimeria species: tenella and maxima.

-these other two LDH proteins are "substantially different" in primary aa sequence: 66-80% identity.

-the 3D structure of the tenella LDH was predicted by computer modeling, and was compared to that of P. falciparum LDH

-the two 3D structures are "very similar"

-the primary aa sequence of the LDH proteins of E. tenella and P. falciparum are only 47% identical.

From these submitted facts, Applicants respectfully submit the following logical conclusions:

1. When two LDH proteins being so dissimilar as E. tenella and P. falciparum (47% identity) are found to have a very conserved 3D structure, then the three Eimeria LDH's which are much more related at the primary aa sequence level (66-80% identity) may be expected to be even more conserved in 3D structure.

2. It is common knowledge that a proteins 3D structure is important for immune-efficacy and the recognition of that protein by the immune system of a host-organism, consequently proteins

with a highly similar 3D structure will also be similar in their immunogenic properties

3. Consequently, as the E. acervulina LDH proved to be effective as a vaccine, therefore, the E. tenella and E. maxima LDH proteins, arguably having a 3D structure very similar to that of E. acervulina LDH, will also be effective in vaccines.

Applicants respectfully submit that the biological variants of E. acervulina LDH, such as the E. tenella and E. maxima LDH proteins, will be equally effective vaccines as the E. acervulina LDH.

Therefore, the present claims are enabled and would not lead to an undue burden of experimentation. The Examiner herself has presented alleged prior art that describe techniques known already in 1975 to determine size and specificity of *Eimeria* LDH enzymes in crude samples. Therefore, Applicants respectfully request withdrawal of the 35 U.S. §112, first paragraph rejection.

Issue Under 35 U.S.C. §102(b)

Claims 1-3, 11, 16-20 and 23-24 stand rejected under 35 U.S.C. §102(b) as being anticipated by Shirley (Parasitology, 71:369-376, 1975). Applicants assert that patentable distinction exists between the cited prior art and the present invention.

Distinction Between the Present Invention and Shirley

As presented in a previous response, Shirley allegedly discloses lactate dehydrogenase enzyme from E. acervulina. Shirley discloses a biochemical characterization of crude samples from Eimeria sporozoites, merozoites and oocysts. The characterization applied is starch-gel electrophoresis and substrate incubation.

The Examiner maintains an inherency argument that the isolated protein of the present invention is present within the mixture disclosed. Furthermore, the Examiner maintains that the vaccine claim is an intended use of the enzyme.

Shirley fails to disclose or suggest a protein expressed *in vitro,* comprising one or more immunoreactive and/or antigenic determinants of *Eimeria* lactate dehydrogenase (LDH), wherein said isolated protein is found intracellularly in Eimeria; a vaccine for the protection of poultry against Coccidiosis comprising an effective amount of an isolated protein comprising one or more immunoreactive and/or antigenic determinants of Eimeria lactate dehydrogenase, wherein said isolated protein is found intracellularly in Eimeria; and an immunogenic fragment of Eimeria lactate dehydrogenase (LDH), wherein said LDH is immunogenically reactive with antiserum raised against the polypeptide of SEQ ID NO:2.

Shirley, at best, discloses a native intact Eimeria LDH protein. Shirley never mentions using these proteins as

vaccines.

Applicants still completely disagree with Examiner's statement that the recitation of "vaccine" is an intended use. The vaccine claims stand alone. A vaccine claims can be clearly patentable, if is novel, even if the protein itself is anticipated. Shirley fails to discuss a vaccine; thus, it is completely impossible for Shirley to anticipate a "vaccine" claim.

Shirley fails to disclose each element of the present invention as set forth in the claims.

Applicants respectfully request withdrawal of the 35 U.S.C. §102(b).

Issue Under 35 U.S.C. §102(b)

Claims 1-3, 11, 16-18 and 23 stand rejected under 35 U.S.C. §102(b) as being anticipated by Kucera (Folia Parasitologica 36(4):295-299). Applicants assert that patentable distinction exists between the cited prior art and the present invention.

Distinction Between the Present Invention and Kucera

As presented in an earlier response, Kucera allegedly discloses lactate dehydrogenase enzyme from E. acervulina. Kucera discloses methods for performing techniques of Shirley (see above) with a certain type of electrophoresis equipment.

Homogenized Eimeria oocysts are used.

The Examiner maintains an inherency argument that the isolated protein of the present invention is present within the mixture disclosed. Furthermore, the Examiner maintains that the vaccine claim is an intended use of the enzyme.

Kucera fails to disclose or suggest a protein expressed *in vitro*, comprising one or more immunoreactive and/or antigenic determinants of *Eimeria* lactate dehydrogenase (LDH), wherein said isolated protein is found intracellularly in Eimeria; a vaccine for the protection of poultry against Coccidiosis comprising an effective amount of an isolated protein comprising one or more immunoreactive and/or antigenic determinants of Eimeria lactate dehydrogenase, wherein said isolated protein is found intracellularly in Eimeria; and an immunogenic fragment of Eimeria lactate dehydrogenase (LDH), wherein said LDH is immunogenically reactive with antiserum raised against the polypeptide of SEQ ID NO:2.

Kucera, at best, discloses a native intact Eimeria LDH protein. Kucera never mentions using these proteins as vaccines.

Again, Applicants completely disagree with Examiner's statement that the recitation of "vaccine" is an intended use. Kucera fails to discuss a vaccine; thus, it is completely impossible for Kucera to anticipate a "vaccine" claim.

Kucera fails to disclose each element of the present invention as set forth in the claims.

Applicants respectfully request withdrawal of the 35 U.S.C. §102(b).

Issue Under 35 U.S.C. §102(b)

Claims 1-3, 16-18 and 23 stand rejected under 35 U.S.C. §102(b) as being anticipated by Nakamura et al (Journal of Veterinary Medical Science, 53(6):1101-1103, 1991. Applicants assert that patentable distinction exists between the cited prior art and the present invention.

Distinction Between the Present Invention and Nakamura et al.

As previously presented, Nakamura et al. allegedly discloses lactate dehydrogenase enzyme from E. acervulina. Nakamura et al. discloses Eimeria enzyme starch-gel electrophoresis, and uses enzymes samples from sporulated oocysts.

The Examiner maintains an inherency argument that the isolated protein of the present invention is present within the mixture disclosed. Furthermore, the Examiner maintains that the vaccine claim is an intended use of the enzyme.

Nakamura et al. fails to disclose or suggest a protein expressed *in vitro*, comprising one or more immunoreactive and/or antigenic determinants of *Eimeria* lactate dehydrogenase (LDH), wherein said isolated protein is found intracellularly in Eimeria; a vaccine for the protection of poultry against

Coccidiosis comprising an effective amount of an isolated protein comprising one or more immunoreactive and/or antigenic determinants of Eimeria lactate dehydrogenase, wherein said isolated protein is found intracellularly in Eimeria; and an immunogenic fragment of Eimeria lactate dehydrogenase (LDH), wherein said LDH is immunogenically reactive with antiserum raised against the polypeptide of SEQ ID NO:2.

Nakamura et al., at best, discloses a native intact Eimeria LDH protein. Nakamura et al. never mentions using these proteins as vaccines.

Again, Applicants completely disagree with Examiner's statement that the recitation of "vaccine" is an intended use. Nakamura et al. fails to discuss vaccine; thus, it is completely impossible for Nakamura et al. to anticipate a "vaccine" claim.

Nakamura et al. fails to disclose each element of the present invention as set forth in the claims.

Applicants respectfully request withdrawal of the 35 U.S.C. §102(b).

Conclusion

All the stated grounds of the rejections have been properly traversed, accommodated or rendered moot. Applicants respectfully submit that the present application is in condition for allowance.

If the Examiner believes for any reason that personal

communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (302) 934-4395, in Millsboro, Delaware.

Pursuant to 37 C.F.R. §§1.17 and 1.136(a), Applicants respectfully petitions for a two month extension of time for filing a response in connection with the present application and the Commissioner is hereby authorized to charge the required fee of $420 to Deposit Account No. 02-2334.

If necessary, the Commissioner is hereby authorized in this, concurrent, and further replies, to charge payment or credit any overpayment to Deposit Account No. 02-2334 for any additional

fees required under 37 C.F.R. §1.16 or under 37 C.F.R. §1.17; particularly extension of time fees.

Respectfully submitted,

Mark W. Milstead
Attorney for Applicants
Registration No. 45,825

Akzo Nobel Pharma Patent Dept.
P.O. Box 318
29160 Intervet Lane
Millsboro, DE 19966
Tel: (302) 933-4034
Fax: (302) 934-4305

MWM

Enclosure: Schaap et al. Journal Article

DIVISION

AM 10: 33

Certificate of Mailing under 37 CFR 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

on October 20, 2004
Date

Signature

Diane Payne
Typed or printed name of person signing Certificate

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

USSN: 10/467,768
Customer No.: 31846
Attorney Docket No.: I-1995.150 US D1

Petition to Refund to Deposit Account (3 pages)
Request for Continued Examination PTO SB30 (1 page)
Fax Cover Sheet of July 27, 2004 (1 page)
Fax History Report of July 27, 2004 (1 page)
Postcard of July 27, 2004 (1 page)
Certificate of Mailing of July 27, 2004 (1 page)
Amendment of July 27, 2004 (17 pages)
Self-Addressed Stamped Postcard